



4160-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2012-N-0001]

Circulatory System Devices Panel of the Medical Devices Advisory Committee; Notice of Meeting

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

This notice announces a forthcoming meeting of a public advisory committee of the Food and Drug Administration (FDA). The meeting will be open to the public.

Name of Committee: Circulatory System Devices Panel of the Medical Devices Advisory Committee.

General Function of the Committee: To provide advice and recommendations to the Agency on FDA's regulatory issues.

Date and Time: The meeting will be held on April 25 and 26, 2012, from 8 a.m. to 6 p.m.

Location: Holiday Inn, Ballroom, 2 Montgomery Village Ave., Gaithersburg, MD 20879. The hotel's phone number is 301-948-8900.

Contact Person: Jamie Waterhouse, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Silver Spring, MD 20993, 301-796-3063, email: Jamie.Waterhouse@fda.hhs.gov, or FDA Advisory Committee Information Line, 1-800-741-8138 (301-443-0572 in the Washington, DC area), and follow the prompts to the desired center or product area. Please call the Information Line for up-to-date information on this meeting. A notice in the Federal Register about last minute modifications that impact a previously announced advisory committee meeting cannot always be published quickly enough

to provide timely notice. Therefore, you should always check the Agency's Web site and call the appropriate advisory committee hot line/phone line to learn about possible modifications before coming to the meeting.

Agenda: On April 25, 2012, the committee will discuss, make recommendations and vote on information related to a supplement to the premarket approval application (PMA) for the HeartWare Ventricular Assist System (HVAS) sponsored by HeartWare, Inc. The HVAS is an implantable electrically powered centrifugal-flow rotary blood pump with external driver and power source(s). It is the first ventricular assist device that does not require the creation of an abdominal pump pocket. The HVAS is indicated for use as a bridge to cardiac transplantation in patients who are at risk of death from refractory, advanced heart failure.

On April 26, 2012, the committee will discuss, make recommendations and vote on information related to the PMA for the Subcutaneous Implantable Cardioverter Defibrillator (S-ICD) System sponsored by Cameron Health, Inc. The S-ICD is the first implantable defibrillator that does not require the implantation of an electrode either on or in the heart. The S-ICD is intended to provide defibrillation therapy for the treatment of life-threatening ventricular tachyarrhythmias. The device is capable of delivering high energy defibrillation shocks as well as bradycardia demand mode cardiac pacing. The study provides data from the treatment of induced acute and chronic episodes of ventricular tachycardia/ventricular fibrillation and spontaneous episodes. In addition to the investigational device exemption study, clinical data were also obtained from using studies outside the United States and registries.

FDA intends to make background material available to the public no later than 2 business days before the meeting. If FDA is unable to post the background material on its Web site prior to the meeting, the background material will be made publicly available at the location of the

advisory committee meeting, and the background material will be posted on FDA's Web site after the meeting. Background material is available at <http://www.fda.gov/AdvisoryCommittees/Calendar/default.htm>. Scroll down to the appropriate advisory committee link.

Procedure: Interested persons may present data, information, or views, orally or in writing, on issues pending before the committee. Written submissions may be made to the contact person on or before April 17, 2012. Oral presentations from the public will be scheduled between approximately 1 p.m. and 2 p.m. on April 25 and 26, 2012. Those individuals interested in making formal oral presentations should notify the contact person and submit a brief statement of the general nature of the evidence or arguments they wish to present, the names and addresses of proposed participants, and an indication of the approximate time requested to make their presentation on or before April 10, 2012. Time allotted for each presentation may be limited. If the number of registrants requesting to speak is greater than can be reasonably accommodated during the scheduled open public hearing session, FDA may conduct a lottery to determine the speakers for the scheduled open public hearing session. The contact person will notify interested persons regarding their request to speak by April 12, 2012.

Persons attending FDA's advisory committee meetings are advised that the Agency is not responsible for providing access to electrical outlets.

FDA welcomes the attendance of the public at its advisory committee meetings and will make every effort to accommodate persons with physical disabilities or special needs. If you require special accommodations due to a disability, please contact AnnMarie Williams, at AnnMarie.Williams@fda.hhs.gov, 301-796-5966, at least 7 days in advance of the meeting.

FDA is committed to the orderly conduct of its advisory committee meetings. Please visit our Web site at <http://www.fda.gov/AdvisoryCommittees/AboutAdvisoryCommittees/ucm111462.htm> for procedures on public conduct during advisory committee meetings.

Notice of this meeting is given under the Federal Advisory Committee Act (5 U.S.C. app. 2).

Dated: March 13, 2012.

Jill Hartzler Warner,

Acting Associate Commissioner for Special Medical Programs.